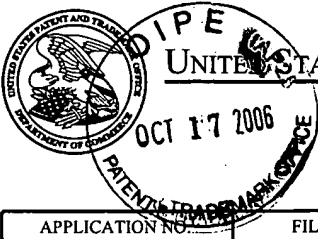


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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,191	07/15/2003	David E. Silverman	A-70013-1/ENB	2339
7590 10/05/2006			EXAMINER	
DORSEY & WHITNEY LLP Suite 3400 Four Embarcadero Center San Francisco, CA 94111-4187			GILBERT, SAMUEL G	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/621,191	<b>Applicant(s)</b> SILVERMAN ET AL.	
	<b>Examiner</b> Samuel G. Gilbert	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,9,10 and 12-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,9,10 and 12-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/15/2006, 2/9/2006</u> | 6) <input type="checkbox"/> Other: ____  |

***Information Disclosure Statement***

The information disclosure statements filed 2/9/2006 and 7/15/2003 have been considered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9, 10, 12, 17-22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Lawin et al (5,792,478).

Claims 1, 17 - the particles set forth in column 3 lines 45 through column 5 line 12 form a non-biodegradable solid in a rectal wall, column 6 lines 18-27 and the carrier may be aqueous or non-aqueous, column 5 lines 13 through 60.

Claim 2 - each of the particles forms a discrete nonbiodegradable solid in the wall.

Claims 3 and 22 - the particles may be oblong, which the examiner is taking to be rod-shaped, column 5 line 5.

Claims 4, 9, 10, 12, 21, and 10 - Lawin et al teaches injecting the material in the area of the internal or external sphincter, abstract and column 6 lines 18-27. The examiner is taking the area to include at least some intersphincteric space.

Claim 18 - the solutions are set forth in column 5 lines 50-50.

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Claim 19 - a needle is set forth in column 5 line 63.

Claim 20 - repairing structurally defective sphincters is set forth in column 6 lines 18-27, it is the examiner's position that the step of repairing would inherently bridge the damaged portion.

Claim 24 - the non-aqueous solution is injected into the rectal wall.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 9, 10, and 12-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,533,717. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are an obvious broadening of the scope of the patented claims.

Claims 1-5, 9, 10, and 12-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,251,063. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are an obvious broadening of the scope of the patented claims.

Claims 1-5, 9, 10, and 12-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,595,910. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are an obvious broadening of the scope of the patented claims.

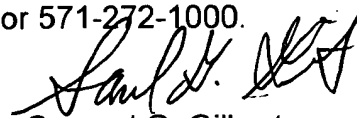
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Samuel G. Gilbert  
Primary Examiner  
Art Unit 3735

sgg

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>					Complete if Known	
					Application Number	To be assigned
					Filing Date	July 15, 2003
					First Named Inventor	DAVID E. SILVERMAN
					Group Art Unit	To be assigned
					Examiner Name	To be assigned
Sheet	1	of	3	Attorney Docket Number A-70013-1/ENB		
<b>U.S. PATENT DOCUMENTS</b>						
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	U.S. Patent Document  Number Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
SG	A1	3,094,122	Gauthier et al.	06/18/1963		
	B1	3,204,634	Koehn	09/07/1965		
	C1	4,351,333	Lazarus et al.	09/28/1982		
	D1	4,424,208	Wallace et al.	01/03/1984		
	E1	4,582,640	Smestad et al.	04/15/1986		
	F1	4,773,393	Haber et al.	09/27/1988		
	G1	4,803,075	Wallace et al.	02/07/1989		
	H1	4,837,285	Berg et al.	06/06/1989		
	I1	5,007,940	Berg	04/16/1991		
	J1	5,067,965	Ersek et al.	11/26/1991		
	K1	5,116,387	Berg	05/26/1992		
	L1	5,158,573	Berg	10/27/1992		
	M1	5,204,382	Wallace et al.	04/20/1993		
	N1	5,258,028	Ersek et al.	11/02/1993		
SG	O1	5,301,682	Debbas	04/12/1994		
	P1					
	Q1					
	R1					
<b>FOREIGN PATENT DOCUMENTS</b>						
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document  Office <sup>3</sup> Number <sup>4</sup> Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant	T <sup>5</sup>
SG	S1	WO 98/17201	PCT	04/30/1998		
	T1	WO 98/17200	PCT	04/30/1998		
	U1	WO 98/01088	PCT	01/15/1998		
	V1	WO 97/45131	PCT	12/04/1997		
	W1	WO 97/19643	PCT	06/05/1997		
SG	X1	AU A-34223/95	AU	05/02/1996		
	Y1					
	Z1					
Examiner Signature	/Samuel Gilbert/ (09/23/2006)			Date Considered		

<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>2</sup> Unique citation designation number. <sup>3</sup> See attached Kinds of U.S. Patent Documents. <sup>4</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>5</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>7</sup> Applicant is to place a check mark here if English Language Translation is attached.

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<b>U.S. PATENT DOCUMENTS</b>						
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		Number Kind Code <sup>2</sup> (if known)				
SG	A2	5,336,263	Ersek et al.	08/09/1994		
	B2	5,451,406	Lawin et al.	09/19/1995		
	C2	5,480,644	Freed	01/02/1996		
	D2	5,490,984	Freed	02/13/1996		
	E2	5,580,568	Greff et al.	12/03/1996		
	F2	5,667,767	Greff et al.	09/16/1997		
	G2	5,695,480	Evans et al.	12/09/1997		
	H2	5,702,361	Evans et al.	12/30/1997		
	I2	5,755,658	Wallace et al.	05/26/1998		
	J2	5,785,642	Wallace et al.	07/28/1998		
	K2	5,792,478	Lawin et al.	08/11/1998		
	L2	5,830,178	Jones et al.	11/03/1998		
	M2	6,251,063	Silverman et al.	06/26/2001		
	N2	6,251,064	Silverman et al.	06/26/2001		
SG	O2	2001/0018548	Silverman et al.	08/30/2001		
	P2					
	Q2					
	R2					
<b>FOREIGN PATENT DOCUMENTS</b>						
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant	T <sup>4</sup>
		Kind Code <sup>2</sup> Office <sup>3</sup> Number <sup>4</sup> (if known)				
	S2					
	T2					
	U2					
	V2					
	W2					
	X2					
	Y2					
	Z2					
Examiner Signature	/Samuel Gilbert/ (09/23/2006)			Date Considered		

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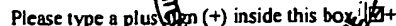
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				Group Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	3	of	3	Attorney Docket Number	A-70013-1/ENB
<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
SG	A3	Donahue, P. et al., "Endoscopic Sclerosis Of The Gastric Cardia For Prevention Of Experimental Gastroesophageal Reflux" (1990) <i>Gastrointestinal Endoscopy</i> , pp. 253-256.			
	B3	Klingman, R.R. et al., "The Current Management of Gastroesophageal Reflux", (1991), <i>Adv. Surg.</i> , Vol. 24, pp. 259-291.			
	C3	Malizia, A. et al., "Migration and Granulomatous Reaction After Periurethral injection of Polytef (Teflon)", (June 1984), <i>JAMA</i> , Vol. 251, No. 24, pp. 3277-3281.			
	D3	O'Connor, K.W. et al., "Endoscopic placement of collagen at the lower esophageal sphincter to inhibit gastroesophageal reflux: a pilot study of 10 medically intractable patients", (1988), <i>Gastrointestinal Endoscopy</i> , Vol. 34, No. 2, pp. 106-112.			
	E3	O'Connor, K. W. et al., "An experimental endoscopic technique for reversing gastroesophageal reflux in dogs by injecting inert material in the distal esophagus", (1984) <i>Gastrointestinal Endoscopy</i> , Vol. 30, No. 5, pp. 275-280.			
	F3	Ortiz, A. et al., "Conservative treatment versus antireflux surgery in Barrett's oesophagus: long-term results of a prospective study", (1996), <i>Brit. Jnl. of Surg.</i> , Vol. 83, 274-278.			
	G3	Politano, V.A., et al., "Periurethral Teflon Injection for Urinary Incontinence", (February 1974) <i>Jnl. Urology</i> , Vol. 111, pp. 180-183.			
	H3	Schulman, C.C. et al., "Endoscopic injections of Teflon to treat urinary incontinence in women", (January 21, 1984) <i>BMJ</i> , Vol. 228, p. 192.			
	I3	Shafik, A., "Intraesophageal Polytef injection for the treatment of reflux esophagitis", (1996), <i>Surgical Endoscopy</i> , pp. 329-331.			
SG	J3	Walker, R.D. et al., "Injectable Bioglass as a Potential Substitute for Injectable Polytetrafluoroethylene", (August 1992), <i>J. Urol.</i> , Vol. 148, pp. 645-647.			
	K3				
	L3				
	M3				
	N3				
	O3				
Examiner Signature	/Samuel Gilbert/ (09/23/2006)			Date Considered	

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<b>Notice of References Cited</b>	Application/Control No. 10/621,191	Applicant(s)/Patent Under Reexamination SILVERMAN ET AL.	
	Examiner Samuel G. Gilbert	Art Unit 3735	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,595,910	07-2003	Silverman et al.	600/29
*	B	US-6,533,717	03-2003	Silverman et al.	600/29
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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